REMARKS

Claims 19, 25-39, and 48 are pending in the application, although claims 28-31 and 34-39 have been withdrawn from consideration. Claims 19-27 and 32-33 stand rejected as anticipated by, or unpatentable over, U.S. Patent Publication No. 2003/0036202 to Teodorcyzk et al. and/or U.S. Patent Publication No. 2002/0160517 to Modzelewski et al. for the reasons of record. In view of the present amendments and remarks, reconsideration of the application is respectfully requested.

1. §112 Issues.

The pending Office Action rejects claims 23 and 24 under §112. The present amendment is believed to correct any §112 problems that may have been present. With respect to the claim limitation "wherein the dye is an IR dye which does not have a substantial absorption in the wavelength range in which the measurement signal for the analyte of interest is detected," it is respectfully submitted that "the totality of all the limitations of the claim and their interaction with each other" provides sufficient definiteness to the claim, and "apprises persons of ordinary skill in the art of the claim scope and, therefore, serves the notice function required by 35 U.S.C. 112, paragraph 2." See, MPEP 2173.05(e).

2. The §102 and §103 Rejections.

a) The Claimed Invention.

Claim 1 has been amended to include the limitations of original claims 22 and 24. All of the subject matter of amended claim 1 is therefore believed to have been examined by the Office's examination of original claims 22 and 24. No new matter has been added to the application.

Amended claim 1 recites a method for automatically determining whether a sample liquid is a test sample or a control sample in the context of measuring a sample liquid for an analyte of interest. The claimed method uses an optical measuring instrument and control samples that have been provided with an IR dye that does not have a substantial absorption in the wavelength range in which the measurement signal for an analyte of interest is detected. The optical measuring instrument is a photometer that measures absorption or remission in the IR range. By using IR light, the photometer measures the sample liquid for the analyte of interest, and additionally determines whether the sample is a control sample or a test sample.

New claim 48 has been added to more particularly point out and distinctly claim subject matter disclosed in the application. No new subject matter has been added to the application.

b) The Rejections Based on Teodorcyzk.

U.S. Patent Publication No. 2003/0036202 to Teodorcyzk et al. is cited against the application. According to the Office, Teodorcyzk discloses a method for determining whether a sample liquid is a test sample or a control sample by using an optical measuring instrument and control samples that have been provided with an IR dye.

It is unclear whether the Office contends that Teodorcyzk discloses applicants' claimed step of using a photometer to measure absorption or remission in the IR range. While the Office states that the dye may be an IR dye, the Office also acknowledges that the Teodorcyzk patent discloses that the dye "has a maximum absorbance of light outside that of hemoglobin." Since the actual quote from Teodorcyzk is that the dye "has a maximum absorbance of visual light outside that of hemoglobin" it would appear that the Office is aware

that Teodorcyzk is limited on its face to the use of visual light, and does not disclose using IR light. See, Teodorcyzk at ¶26.

In fact, when considered as a whole, applicants respectfully submit that Teodorcyzk teaches away from the use of IR light by stating that the light should have a wavelength in the visible spectrum of between 450 nm and 750nm. See, Teodorcyzk at ¶71. Again, this is consistent with Teodorcyzk's earlier disclosure that the dye "has a maximum absorbance of visual light outside hemoglobin. See, Teodorcyzk at ¶26. Moreover, the only example of Teodorcyzk that uses a colorimetric method uses visible light at the 700 nm wavelength, again teaching away from the use of IR light.

In view of the above, applicants respectfully submit that Teodorcyzk does not teach applicants' claimed step of using a photometer to measure absorption or remission in the IR range. Since that claim limitation is not present in Teodorcyzk, the §102 rejections based on Teodorcyzk should be withdrawn.

c) The Rejections Based on Modzelewski.

U.S. Patent Publication No. 2002/0160517 to Modzelewski et al. is cited against the application. According to the Office, Modzelewski discloses distinguishing between a test sample and a control sample by analyzing aspects of the spectral curve of a sample liquid over a wavelength range of between 500 nm and 900 nm. The Office further contends that Modzelewski discloses that any dye may be used as long as the dye produces a detectable difference in measured values at two selected wavelengths.

Applicants respectfully submit that the Modzelewski reference does not teach applicants' claimed step of using a dye that is an IR dye which does not have a substantial

absorption in the wavelength range in which the measurement signal for the analyte of interest is detected. Since that claim limitation is not disclosed by Modzelewski, the §102 rejections based on Modzelewski should be withdrawn.

As to the specific teachings of Modzelewski, Modzelewski teaches specifically that the dye may be "any suitable dye [effective] to modify the spectral curve of the glucose control solution, as long as it produces a detectable difference in measured results at the two selected LED wavelengths." Modzelewski at ¶100. The two selected wavelengths are taught to be in the 600 nm to 700 nm range, and particularly to be the 610 nm and 660 nm wavelengths where "[i]t was noted by the present inventors that … the shape of the spectral curve for blood is substantially similar irrespective of glucose level." Modzelewski at ¶70. While Modzelewski includes the standard statement that other wavelengths may be used, Modzelewski provides no teaching as to how any wavelength outside the 600 nm to 700 nm wavelength would be effective for distinguishing test samples from control samples. The only teaching of Modzelewski on this point is that all blood samples have the same shape of spectral curve at the 600 nm to 700 nm wavelength, regardless of glucose levels, and that spectral curves for samples that have one of Modzelewski's dyes have a different spectral curve in that wavelength range.

Accordingly, instead of teaching that IR light may be used to distinguish between test samples and control samples, Modzelewski teaches only that blood samples may be distinguished from control samples by comparing the spectral curves at the 600 nm to 700 nm range (more particularly 610 nm and 660 nm). If the spectral curve shows the smooth "U" shape indicative of blood samples, the machine identifies it as a blood sample. If the spectral curve shows a "deflected" shape indicative of the presence of a dye, the machine identifies it as a

control sample. Modzelewski never teaches or suggests that all blood samples have the same shape of spectral curve at IR wavelengths, or that an IR dye would be effective for providing control samples with a distinguishing spectral curve over the 600 nm to 700 nm wavelength range where all blood samples have the same-shaped curve.

Similarly to the above, Modzelewski does not teach applicants' claimed step of using the measurement of absorption or remission in the IR range as the basis for distinguishing between a test sample and a control sample. While Modzelewski teaches broadly that reflectance may be measured over the 500 nm to 900 nm wavelength range, he does not use the IR portion of that range to distinguish between test samples and control samples. As noted above, Modzelewski's teaching of how to distinguish between test samples and control samples is limited to comparing spectral curves in the 600 nm to 700 nm range where Modzelewski has found the consistent blood-distinguishing shape to occur.

In view of the above, applicants respectfully submit that Modzelewski's illustration of a spectral curve over a 500 nm to 900 nm wavelength range, coupled with his teaching that "any suitable dye [effective] to modify the spectral curve of the glucose control solution" can be used "as long as it produces a detectable difference in measured results at the two selected LED wavelengths," does not teach or suggest the use of the IR range to distinguish test samples from control samples in the absence of some teaching as to how that could be done. Modzelewski's teaching that the 600 nm to 700 nm wavelength range may provide a basis for distinguishing test samples from control samples simply does not lead persons of skill in the art to use an IR wavelength that is not taught to have the blood-sample-identifying characteristic. Accordingly, the rejections based on Modzelewski should be withdrawn.

3. Conclusion.

The cited references, either alone or in combination, do not teach or suggest applicants' claimed invention. Reconsideration of the application is respectfully requested.

Respectfully submitted,

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